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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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ARNOLD & PORTER LLP
ATTN: IP DOCKETING DEPT.
555 TWELFTH STREET, N.W.
WASHINGTON, DC 20004-1206

EXAMINER	
CLOW, LORI A	
ART UNIT	**PAPER NUMBER**
1631	

DATE MAILED: 03/09/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/922,293	CONNER ET AL.	
	Examiner	Art Unit	
	Lori A. Clow, Ph.D.	1631	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *09 December 2003*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *10-12 and 14-19* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *10-12 and 14-19* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Applicant's arguments filed 9 December 2003 have been fully considered. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

Claims 10-12, are 14-19 are currently pending. Claims 1-9 and 13 have been cancelled.

Election/Restrictions

Applicant argues that the election of a single nucleic acid sequence is improper and that no serious burden would result by the search and examination of at least ten nucleotide sequences. This is not persuasive and the Examiner would like to point Applicant to the Previous Office Action, mailed 9 September 2003, in which the Examiner cited reference to MPEP 803.04. Applicant's argument are therefore not found persuasive for the reasons set forth in the Restriction/Election Requirement. In the requirement, specific distinctions between the multiple sequences were set forth and as such the requirement is still deemed proper and is made FINAL.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 10-12 and 14-19 remains rejected under 35 USC 101 for the reasons stated in the Previous Office Action.

Applicant argues that the present specification describes many objectives that are met by the instant invention, including using the claimed nucleic acid molecules for obtaining protein molecules. However it is maintained that the specification identifies no partial or full open reading frame encoding any protein or fragment thereof and none is apparent. The specification does not assign any particular biological function to any protein that may be encoded by SEQ ID NO. 1 and none is apparent.

None of the other uses disclosed in the specification is particular to the claimed SEQ ID NO. 1 Rather, they are general to all.

All other uses disclosed are not deemed to be specific as using the nucleic acids for determining polymorphisms, molecular tags, expression studies, mapping, and so forth, are not particular to the claimed nucleic acid. General discussion of uses of nucleic acids does not meet the requirement for a specific utility. In addition, to reasonably confirm that full or partial protein sequences were encoded and determine how to use such proteins would require further experimentation and thus is not a substantial utility. Identifying and studying the properties of a nucleic acid to determine if it encodes a protein and then identifying and studying the properties of the protein itself or the mechanisms in which the protein is involved does not define a "real world" context or use.

Applicant further argues that these uses are analogous to a microscope. A microscope is useful for determining structure of *any* sample of interest at the macroscopic, microscopic or molecular level, depending on the type of microscope. It is a generally useful tool for a wide

range of specific uses. One does not usually use a microscope to study related microscopes. In contrast, Applicant argues that the claimed nucleic acid molecules are useful to detect or measure nucleic acid molecules that possess a certain level of structural relatedness to the claimed nucleic acid molecules, the level of relatedness being defined by hybridization to the claimed nucleic acid molecules. However, the specification discloses *no* nucleic acid molecule that hybridizes with the claimed nucleic acid molecules that does *not* consist or comprise SEQ ID NO: 1or its complement. In order for hybridization between two nucleic acid molecules to occur, they must share at least some nucleotide sequence that is fully complementary. The length of fully complementary sequence required to detect hybridization depends primarily on the stringency of the specific hybridization conditions employed, the lower the stringency the shorter the length of fully complementary sequence required. The specification also fails to disclose any hybridization conditions required for detecting nucleic acid molecules that do *not* contain the nucleotide sequence of any of SEQ ID NO: 1 or its complements (other than subsequences of SEQ ID NO: 1), in addition to failing to disclose any source for such nucleic acid molecules.

Further, a microscope has a specific and substantial utility of magnifying images to allow the visualization of items too small to be seen by the unaided eye. This utility is specific for a microscope and is based on the physical structure of the lenses and mirrors present within the microscope. Applicants are effectively arguing that a nucleic acid and microscope are analogous because they can be used as a research tool. However, the claimed nucleic acid can only be used to detect sequences that themselves have no specific and substantial utility. This is analogous to the disclosure of a microscope containing a slide which contains an unknown smear of matter and providing claims to the unknown smear of matter. In regards to SEQ ID NO: 1, it is a

fragment of larger sequence that has no described function that would allow one to identify a specific plant protein product as recited by the claims. With respect to the detection of polymorphisms being a specific and substantial utility, the argument is not convincing because the detection of a polymorphisms is not useful until the polymorphisms is associated with a disease or other specific characteristic of interest to the public.

All arguments pertaining to the utility of the claimed invention with respect to studying the corresponding genomic DNA and mRNA found in *Arabidopsis thaliana*, would also apply to any homologous nucleic acid molecules found in other plant species. In so much as the specification fails to describe a specific and substantial utility for the corresponding nucleic acids in *Arabidopsis thaliana*, so does it fail to describe a specific and substantial utility for the corresponding nucleic acids in other plant species.

Applicants cite *Carl Zeiss Stiftung v. Renishaw PLC* in support of their position that utility has been established. However, this decision is with respect to a mechanical device and not a laboratory reagent or research tool. Furthermore, applicant mischaracterizes the findings in this decision. This decision concerned claim interpretation and the CAFC found that the district court had erred in their interpretation of what the claim embraced and thus what was required to establish utility. The claimed device was found to fulfill the stated objective of mounting a stylus by the CAFC. These facts do not correspond to the instant specification.

Applicant asserts that the Examiner provides no evidence challenging the disclosed utilities for the presently claimed nucleic acid molecules and that the Examiner attempts to undermine the existing utilities by stating that they are "nonspecific uses that are applicable to nucleic acid(s) or proteins in general". Applicant bases the argument on a golf club.

This is not persuasive because while the specification teaches that the claimed nucleic acid molecules "*may be employed* to obtain other nucleic acid molecules" (emphasis added), the specification does not indicate that any such nucleic acid molecules *had been* obtained, nor does it describe any characteristics possessed by such nucleic acid molecules. As to whether such molecules could, in fact, be obtained, the Office can neither prove nor disprove the assertion because the Office does not have laboratory facilities. At the time the application had been filed, future experimentation on the part of one skilled in the art would have been required to determine which, if any, other plant species contained nucleic acid molecules that could have been obtained using the claimed invention, and under what experimental conditions.

In this context, the claimed invention does not compare to a golf club, because one knows what a golf ball is and how to use the golf club to hit it, whereas the specification does not disclose or describe with particularity any known useful nucleic acid molecule that can be obtained, such as the corresponding promoter - it simply invites the skilled artisan to provide such information by further experimentation.

Substantial utility means that "one skilled in the art can use a claimed discovery in a manner which provides some *immediate* benefit to the public," *Nelson v. Bowler*, 206 USPQ2d 881, 883 (CCPA 1980) (emphasis added). Since the specification does not describe the corresponding promoter, or any other specific nucleic acid molecule, sufficient to inform one skilled in the art that it has been isolated, there can be no "*immediate* benefit to the public" in using the claimed nucleic acid molecule in this capacity; "a patent is not a hunting license. It is not a reward for the search, but compensation for its successful conclusion," *Brenner* at page 696.

Claims 10-12 and 14-19 are also rejected under 35 U.S.C. § 112, first paragraph. Specifically, since the claimed invention is not supported by a specific, substantial, and credible utility, or, alternatively, a well established utility for the reasons set forth above, one skilled in the art would not know how to use the claimed invention.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 10-12 and 15-18 remain rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention for reasons set forth in the previous Office Action.

Applicant argues that the Examiner relies on *Regents of the University of California v. Eli Lily and Co.*, 119 F.3d 1559, 43 U.S.P.Q.2d 1398 (Fed. Cir. 1997) for support that proper written description for a claim directed to nucleic acid sequences requires nothing less than the actual disclosure of every sequence encompassed by that claim. Applicant argues that the present case is clearly different because the present claims "distinguish the claimed genus from other" and define "structural features commonly possessed by members of the genus that distinguishes them from others," unlike the claims at issue in *Eli Lily. Id.* At 1568-69 ("a cDNA is not defined or described by the mere name 'cDNA'...but requires a kind of specificity usually achieved by

means of the recitation of the sequence of nucleotides that make up the DNA."). This is not found persuasive because in the instant case, the specification fails to provide written description for specific "structural features commonly possessed by members of the genus" of SEQ ID NO: 1. The Examiner maintains that the specification discloses SEQ ID NO: 1, which corresponds in some undefined way to cDNA/genomic DNA encoding plant species of protein/nucleic acid. SEQ ID NO: 1 per se meets the written description and enablement provisions of 35 USC 112, first paragraph. However, claims 10-12 are directed to encompass gene sequences, and fragments of sequences of SEQ ID NO: 1, corresponding sequences from other species, mutated fragment sequences, allelic variants, splice variants, sequences which hybridize and so forth.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 11 and 12 remain rejected under 35 U.S.C. 102(b) as being anticipated by GenBank Accession Number D30807 (8 March 1995), as evidenced by Meinkoth et al. (Ana. Biochem. (1984) Vol. 138, pages 267-284).

Applicant argues that the Examiner has not presented any evidence, intrinsic or otherwise, in support of the proposition that D30807 would necessarily hybridize to SEQ ID NO: 1. The Examiner respectfully apologizes for lack of inclusion of evidence that D30807 would hybridize to SEQ ID NO: 1 under the conditions presented in claims 11 and 12.

In order to give scientific evidence for the basis of this rejection, melting temperature of

the cited nucleic acid had been calculated based on the formula (pp. 269, formula number 5) disclosed in Meinkoth et al. (Hybridization of nucleic acids immobilized on solid supports: Analytical Biochemistry, 1984, vol. 138, pp. 267-284). The melting temperature of the cited nucleic acid was calculated under the wash conditions set forth in the claim (2.0 X SSC at 50°C) The salt concentration (in molarity) was calculated based on the disclosure by Meinkoth et al. (pp. 267, footnote), resulting in 0.3 M of sodium concentration. The resulting melting temperature was calculated to be 85.5°C. Based on this calculation, the cited nucleic acid acid has a melting temperature that is above the claimed incubation temperature, thus fully capable of being hybridized to nucleic acid of SEQ ID NO: 1, rendering the claim anticipated.

No claims are allowed.

Inquiries

Papers related to this application may be submitted to Technical Center 1600 by facsimile transmission. Papers should be faxed to Technical Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993) (See 37 CFR § 1.6(d)). The CM1 Fax Center number is either (703) 308-4242, or (703) 308-4028.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lori A. Clow, Ph.D., whose telephone number is (571) 272-0715. The examiner can normally be reached on Monday-Friday from 10 am to 6:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael P. Woodward, Ph.D., can be reached on (571) 272-0722.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Legal Instrument Examiner, Tina Plunkett, whose telephone number is (703) 305-3524, or to the Technical Center receptionist whose telephone number is (571) 272-0549.

March 2, 2004
Lori A. Clow, Ph.D.
Art Unit 1631
Lori A. Clow

MARJORIE MORAN
PATENT EXAMINER
Marjorie A. Moran